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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16CM]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Cooperative Re-engagement Controlled Trial (CoRECT) - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC),

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a new three year OMB approval for information collection for a new research study entitled "The Cooperative Re-engagement Controlled Trial (CoRECT)". The purpose of the study is to evaluate a combined health department and clinic intervention to improve engagement in HIV care. Increasing the number of people living with HIV who access HIV care and achieve viral load suppression addresses one of the priorities of the National HIV/AIDS Strategy. The data collection is authorized under the Section 301 of the Public Health Service Act (42 U.S.C. 241)

The CoRECT Study data collection is comprised of six core components: 1. electronic clinic data abstraction (Electronic Medical Record (EMR) abstraction will be conducted by project clinic staff at each project clinic to develop the clinic-based "Out of Care" list; 2. electronic surveillance data abstraction (Electronic surveillance data abstraction will be conducted by project health department staff at each health department to develop the health department based "Out of Care" list); 3. a "Barriers to Care" survey (These surveys will provide information regarding barriers to accessing healthcare (e.g., transportation, financial assistance, housing, substance abuse

services, etc.); 4. a “Standard of Care” survey (Investigators will administer this survey to clinic managers, at baseline and every six months during the study period to assess how the delivery of health services has evolved over time) 5. a Participant Eligibility Disposition form (a listing of potential out-of-care patients will be reviewed to determine those who appear to be out-of-care, as determined by study eligibility, versus those who meet criteria for exclusion); and 6) a Case Conference form (project health department staff will determine if potentially eligible patients met criteria for inclusion in the study and if so randomization will occur). Prospective data collection will provide information about participant’s baseline characteristics including sex, race/ethnicity, HIV exposure risk category, CD4 and viral load test results, date of first clinic visit, and insurance status.

HIV antiretroviral therapy (ART) can durably suppress the plasma HIV viral load, which improves individual survival and dramatically reduces further HIV transmission. Increasing the number of people living with HIV who access HIV care and achieve viral load suppression is a priority of the National HIV/AIDS Strategy. Within the continuum of HIV care in the United States, improvements in linkage to and retention in effective care provide the greatest opportunity to improve rates of HIV viral

suppression. It is estimated that of the 1.2 million persons living with HIV in 2011, only 40% were engaged in HIV medical care and only 30% achieved viral suppression.

HIV clinical trials with enhanced case management have demonstrated that interventions provided by the health department can improve linkage to HIV care and interventions provided by the clinic can improve retention in HIV care. Although linkage to care has improved in many health department jurisdictions, being linked to care is not enough. There is a need to ensure that: (i) people diagnosed with HIV and linked to care are engaging medical care (i.e., attending their enrollment appointment and returning for follow-up medical appointments); and (ii) people who have disengaged from HIV care (i.e., have missed medical appointments and have not been seen in clinic for more than 6 months) are able to efficiently re-engage in care. There have been no randomized controlled studies using a Data-to-Care approach to identify and re-engage out of care persons. Controlled studies such as the CoRECT study are critical to determine the effectiveness of HIV prevention interventions.

The CoRECT study is a randomized controlled trial that seeks to establish a data-sharing partnership between health departments and HIV care clinical providers to identify HIV-

infected persons who are out of care and evaluate an intervention that aims to have randomized participants: (a) link to an HIV clinic; (b) remain in HIV medical care; (c) achieve HIV viral load suppression within 12 months; and (d) achieve durable HIV viral load suppression over 18 months.

The study is funded by CDC through cooperative agreements with the Connecticut State Department of Public Health (in collaboration with Yale University School of Medicine), the Massachusetts State Department of Public Health, and the Philadelphia Department of Public Health. The total burden hours are 1,731.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)
CoRECT Study Coordinator	Electronic transmittal of surveillance variables	3	4	1
Clinic Data Manager	Electronic transmittal of clinical variables	46	4	1
CoRECT Study Participants	Barriers to Care Survey	1,200	1	30/60

Clinical Nurse Coordinator	Standard of Care Survey	46	2	45/60
Clinic Data Manager	Case Conference Session	46	12	1
CoRECT study Coordinator (health department)	Case Conference Session	3	12	1
CoRECT Study Coordinator (health department)	Participant Eligibility Disposition form	3	12	1
Clinic data manager	Cost analysis form-baseline	46	1	1
CoRECT Study Coordinator	Start-up cost analysis form-Health department	3	1	1
Clinic Data Manager	Start-up Cost Analysis form-Clinic	46	1	1
CoRECT Study Coordinator	Annual Costs Analysis form-Health department	3	2	1.5
Clinic Data Manager	Annual Costs Analysis form-Clinic	46	2	1.5

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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
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